



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,419	06/09/2006	Thierry Dubuffet	SERVIER 500 PCT	4880

25666 7590 05/16/2007  
THE FIRM OF HUESCHEN AND SAGE  
SEVENTH FLOOR, KALAMAZOO BUILDING  
107 WEST MICHIGAN AVENUE  
KALAMAZOO, MI 49007

EXAMINER
----------

BARKER, MICHAEL P

ART UNIT	PAPER NUMBER
----------	--------------

1626

MAIL DATE	DELIVERY MODE
-----------	---------------

05/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,419	<b>Applicant(s)</b> DUBUFFET ET AL.	
	<b>Examiner</b> Michael P. Barker	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 6/9/06, Preliminary Amendment.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/9/06; 3/20/07</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant canceled **Claims 1-6** and added **Claims 7-12** via a Preliminary Amendment. Therefore, **Claims 7-12** are pending in this Application.

#### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on March 7, 2005 and June 27, 2005 were correctly filed. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS's were considered by the Examiner. Please refer to Applicant's copies of PTO-1449, submitted herewith.

#### ***Obviousness Double Patenting***

The nonstatutory double patenting rejection is based on a judicially-created doctrine based in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

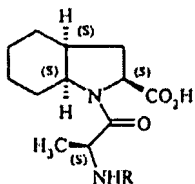
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome the provisional rejection based on a nonstatutory double patenting. Registered attorneys or agents of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1626

**Claim 7** and dependent claims **8-12** are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over: **Claim 7** and dependent claims **8-12** of copending Application 10/582,283. The rejection is *provisional* since the conflicting claims are not patented.

Basis for Rejection:

The instant invention is broader in scope than the conflicting invention. Both inventions disclose a process of synthesizing compounds and pharmaceutically acceptable salts of the



general formula (I),

Formula (III) of the conflicting invention limits **R'** (corresponding to formula IV of the instant invention) to *ethyl pentanoate*. However, **R'** in the instant invention is a *protecting group for the amino function*.

There are differences between the instant and conflicting inventions. The conflicting invention is slightly narrower than the instant invention. The conflicting invention is optimized as compared to the instant invention, achieved through routine experimentation. The conflicting invention anticipates the instant invention, inasmuch as a species anticipates a genus.

***Claim Rejections - 35 USC § 102***

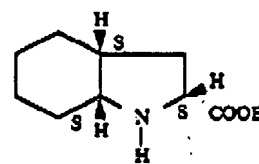
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

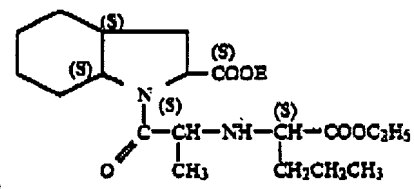
Art Unit: 1626

**Claims 7, 8, 10, and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,914,214, issued April 3, 1990. **Claim 1** of the '214 patent anticipates the instant **Claim 7**, when drawn to formula (IIIa).

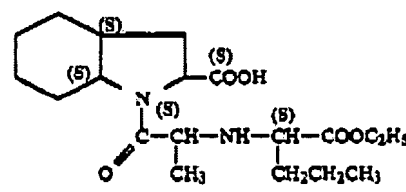


'214 Patent: In **Claim 1**, a compound of formula (IX), , wherein E is lower alkyl or benzyl (E = benzyl: see col. 8, lines 35-36), is condensed with a compound of

formula (VI), 
$$\text{HO}-\text{OC}-\underset{\text{CH}_3}{\overset{\text{(S)}}{\text{CH}}}-\text{NH}-\underset{\text{CH}_3}{\overset{\text{(S)}}{\text{CH}}}(\text{CH}_2\text{CH}_2\text{CH}_3)-\text{CO}-\text{OC}_2\text{H}_5$$
 , "in an alkaline medium in the presence of a catalyst for peptide synthesis such as dicyclohexylcarbodiimide in the presence of



1-hydroxybenzotriazole," to yield the compound of formula (X),



which is deprotected, resulting in the compound of formula (I), which is converted into the tert-butylamine salt. Claims 2 to 5 narrow Claim 1 by specifying the protecting groups used, as well as more specific methods of hydrogenation, including palladium catalysis.

This rejection does not include **Claims 9, 11, or 12** because the '214 patent does not relate to formula (IIIb) of the instant invention.

Art Unit: 1626

***Claim Rejections - 35 USC § 102(e)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 7, 9, 11, and 12** are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,060,842, issued June 13, 2006, with an international filing date of July 23, 2002. The '842 patent at col. 2, line 52 through col. 3, line 50, discloses a process which anticipates Applicant's invention, wherein the benzyl ester of formula (IIIb) is utilized as opposed to (IIIa).

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

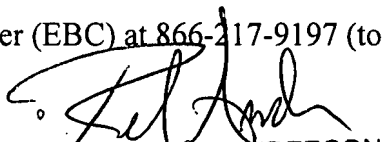
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1626

applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael P. Barker  
Patent Examiner, AU 1626

  
REBECCA ANDERSON  
PATENT EXAMINER

(for) Joseph McKane  
Supervisory Patent Examiner, AU 1626